Meat and Poultry Inspection Regulations

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Field
Operations

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Change 97-3

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

CHANGE TRANSMITTAL SHEET

☐ DIRECTIVE
☐ REVISION
☐ AMENDMENT
☐ OTHER

CHANGE 97-3 MEAT AND POULTRY INSPECTION REGULATIONS	97-3	SEP 25 1997

I. PURPOSE

This document transmits changes to Part 381 of the MPI Regulations. These changes were published in the Federal Register on July 25, 1996 (61 FR 38806, Docket No. 93-016F), Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems.

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove	Insert
Pages i, ii, iii, iiia, 15, 16, 21, 22, 44a, 44b, 155, 156, 179 and 180	Pages i, ii, iii, iiia, 15, 15a, 21, 22, 44a, 44a(1), 44a(2), 44a(3), 44a(4), 44a(5), 44b, 155, 156, 179 and 180

SUBCHAPTER C - MANDATORY POULTRY PRODUCTS INSPECTION

Pages i, ii, iii, iv, 19, 20, 25, 26, 44a, 99, 100, 104a and 105	Pages i, ii, iii, iv, 19, 20, 21a, 25, 26, 48a, 48b, 48c, 48d, 48e, 99, 100, 104a, 104b and 105

SUBCHAPTER E - REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

Pages i, 1, 2, 3, 4, 5, 6, 7, 8 and 9

This covers changes effective as of July 25, 1996.

DISTRIBUTION: M91, M93, M94, M95, CM3, S03, ABB, TRA, PRD, Inspection Offices

OPI: OPPDE

EFFECTIVE DATES: July 25, 1996, however these rules are not applicable until the dates listed below.

Applicability dates (1) The HACCP regulations set forth in 9 CFR Part 417 and related provisions set forth in 9 CFR 304, 317, and 381 parts will be applicable as follows:

- In large establishments, defined as all establishments with 500 or more employees, on January 26, 1998.
- In smaller establishments, defined as all establishments with 10 or more employees but fewer than 500, on January 25, 1999.
- In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million, on January 25, 2000.
- The Sanitation SOP's regulations set forth in 9 CFR 416 will be applicable on January 27, 1997.
- The E. coil process control testing regulations set forth in 9 CFR 310.25(a) and 381.94(a) will be applicable on January 27, 1997.
- The Salmonella pathogen reduction performance standards regulations set forth in 9 CFR 310.25(b) and 9 CFR 381.94(b) will be applicable simultaneously with applicability dates for implementation of HACCP.

Margaret K. Glavin

Deputy Administrator
Office of Policy, Program Develop
and Evaluation

Attachment

CHAPTER III - FOOD SAFETY AND INSPECTION SERVICE
(MEAT AND POULTRY INSPECTION)

DEPARTMENT OF AGRICULTURE

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(§ 304.2(e) continued)

Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(f) Inspection may be refused in accordance with humane slaughter and handling provisions of the Act (21 U.S.C. 603(b)) and the applicable rules of practice.

* § 304.3 Conditions for receiving inspection. *

* (a) Before being granted Federal inspection, an establishment shall have developed *
* written sanitation Standard Operating Procedures, as required by part 416 of this chapter. *
* (b) Before being granted Federal inspection, an establishment shall have conducted a *
* hazard analysis and developed and validated a HACCP plan, as required by §§ 417.2 and 417.4 *
* of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 *
* days, during which period the establishment must validate its HACCP plan. *
* (c) Before producing new product for distribution in commerce, an establishment shall *
* have conducted a hazard analysis and developed a HACCP plan applicable to that product in *
* accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the *
* new product is produced for distribution in commerce, the establishment shall validate its *
* HACCP plan, in accordance with § 417.4 of this chapter. *

PART 305-OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 305.1 Official numbers.

(a) An official number shall be assigned to each establishment granted inspection. Such number shall be used to identify all inspected and passed products prepared in the establishment. More than one number shall not be assigned to an establishment.

(b) Two or more official establishments under the same ownership or control may be granted the same official number, provided a serial letter is added in each case to identify each establishment and the products thereof.

(c) When inspection has been granted to any applicant at an establishment, it shall not be granted to any other person at the same establishment. However, persons operating as separate entities in the same building or structure may operate separate establishments therein only under their own grant of inspection. All such persons operating separate establishments in the same building or structure shall be responsible for compliance with the Act and regulations in their own establishments, which shall include common areas, e.g., hallways, stairways, and elevators.

§ 305.2 Separation of official establishments.

(a) Each official establishment shall be separate and distinct from any unofficial establishment except a poultry products processing establishment operated under Federal inspection under the Poultry Products Inspection Act or under State inspection.

(b) The slaughter or other preparation of products of horses, mules, or other equines required to be conducted under inspection pursuant to the regulations in this subchapter shall be done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared.

(c) Inspection shall not be inaugurated in any building, any part of which is used as living quarters, unless the part for which inspection is solid concrete, brick, wood, or similar material and the floors, walls, and ceilings are without openings that directly or indirectly communicate with any part of the building used as living quarters.

§305.3 Sanitation and adequate facilities.

Inspection shall not be inaugurated if an establishment is not in a sanitary condition nor unless the establishment agrees to maintain a sanitary condition and provides adequate facilities for conducting such inspection.

§ 305.4 Inauguration of inspection.

When inspection is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the operator of the establishment of the requirements of the regulations in this subchapter. If the establishment, at the time inspection is inaugurated, contains any product which has not theretofore been inspected, passed, and marked in compliance with the regulations in this subchapter, the identity of the same shall be maintained, and it shall not be distributed in commerce, or otherwise subject to the requirements of such regulations, or dealt with as inspected and passed under the regulations. The establishment shall adopt and enforce all necessary measures and shall comply with all such directors as the circuit supervisor may prescribe, for carrying out the purposes of this section.

§ 305.5 Withdrawal of inspection; statement of policy.

(a) The Administrator is authorized to withdraw inspection from an official establishment where the sanitary conditions are such that its products are rendered adulterated, or for failure of the operator to destroy condemned products as required by the Act and regulations in this subchapter. Inspection may be withdrawn in accordance with section 401 of the Act and the applicable rules of practice.

(b) The assignment of inspectors may be temporarily suspended, in whole or in part, by the Administrator to the extent it is determined necessary to avoid impairment of the effective conduct of the program when the operator of any official establishment or any subsidiary therein, or any officer, employee, or agent of any such operator or any subsidiary therein, acting within

the scope of his office, employment, or agency, threatens to forcibly assault or forcibly assaults, intimidates, or interferes with any program employee in or on account of the performance of his official duties under the Act, unless promptly upon the incident being brought by an authorized supervisor of the program employee to the attention of the operator of the establishment the operator (1) satisfactorily justifies the incident, (2) takes effective steps to prevent a recurrence, or (3) provides acceptable assurance that there will not be any recurrences. Such suspension shall remain in effect until one of such actions is taken by the operator: Provided, That upon request of the operator he shall be afforded an opportunity for an expedited hearing to show cause why the suspension should be terminated.

(c) Inspection service may be temporarily suspended, in whole or in part, at an official establishment, by the Administrator, to the extent that it is determined necessary to prevent inhumane slaughtering or handling in connection with slaughter of livestock as defined in § 301.2(kk) (9 CFR 301.2(kk)). The Administrator shall notify the operator of an establishment orally or in writing, as promptly as circumstances permit, of such suspension and the reasons therefor. Such suspension shall remain in effect until the operator of the establishment takes effective steps to prevent a recurrence, or provides other satisfactory assurances that there will not be any recurrences. Upon request, the operator shall be afforded an opportunity for a hearing to show cause why the suspension should be terminated.

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PART 308-SANITATION

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.53.

§ 308.1 Examination and specifications for equipment and sanitation prior to granting inspection.

Prior to the inauguration of inspection, an examination of the establishment and premises shall be made by a Program employee and the requirements for sanitation and the necessary facilities for inspection shall be specified by him in accordance with the regulations in this part and Part 307 of this subchapter. The provisions of Part 416 of this chapter also apply.

§ 308.2 Drawings and specifications to be furnished in advance of construction.

Drawings and specifications as prescribed in § 304.2 of this subchapter for remodeling and official establishment, or part thereof, and for any new structures to be used in an official establishment, or part thereof, shall be submitted to the Administrator and approval obtained for the plans in advance of construction.

§ 308.3 Establishments; sanitary condition; requirements.

(a) Official establishments shall be maintained in sanitary condition, and to this end * the requirements of this section shall be complied with. The provisions of part 416 of this * * chapter apply to all establishments, except establishments that are exempt in accordance with * * section 303.1 of this chapter. *

(b) There shall be abundant light, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary condition.

(c) There shall be an efficient drainage and plumbing system for the establishment and premises, and all drains and gutters shall be properly installed with traps and vents approved by the circuit supervisor.

(d)(1) The water supply shall be ample, clean, an potable, with adequate facilities for its distribution in the plant and its protection against contamination and pollution. Every establishment shall make known and, whenever required by the circuit supervisor, shall afford opportunity for inspection of the source of its water supply, the storage facilities, and the distribution system. Equipment using potable water shall be so installed to prevent back-siphonage into the potable water system. Nonpotable water is permitted only in those parts of official establishments where no edible product is handled or prepared, and then only for limited purposes such as on ammonia condensers not connected with potable water supply, in vapor lines serving inedible product rendering tanks, in connection with equipment used for hashing and washing inedible products preparatory to tanking, and in sewer lines for moving heavy solids in the sewage. Nonpotable water is not permitted for washing floors, areas, or equipment involved

in trucking materials to and from edible product departments nor is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding, areas, or runways within the slaughtering department. In all cases, nonpotable waterlines shall be clearly identified and shall not be cross-connected with the potable water supply unless this is necessary for fire protection and such connection is of a type with an adequate break to assure against accidental contamination, and is approved by local authorities and by the circuit supervisor.

(2) The circuit supervisor may permit the reuse of water in vapor lines leading from deodorizers used in the preparation of lard and similar edible product packed in hermetically sealed containers, provided:

(i) The reuse is for the identical original purpose.

(ii) All pipelines, reservoirs, tanks, cooling towers, and like equipment employed in handling the reused water are so constructed and installed so they can be cleaned and drained, and are kept clean.

(3) Approval for the reuse of water other than as specified in paragraph (d)(2) of this section or in § 318.305(h) shall be obtained from the Administrator in specific cases.

(4) An ample supply of water at not less than 180°F. shall be furnished and used for the cleaning of inspection equipment and other equipment, floors, and walls which are subject to contamination by the dressing or handling of diseased carcasses, their viscera, and other parts. Whenever necessary to determine compliance with this requirement, conveniently located thermometers shall be installed by the operator of the official establishment to show the temperature of the water at the point of use.

(5) Hot water for cleaning rooms and equipment other than those mentioned in subparagraph (4) of this paragraph shall be delivered under pressure to sufficient convenient outlets and shall be of such temperature as to accomplish a thorough cleanup.

(e) The floors, walls, ceilings, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish as will make them susceptible of being readily and thoroughly cleaned. The floors shall be kept watertight. The rooms and compartments used for edible product shall be separate and distinct from those used for inedible product.

(f) Rails should be located and passageway space provided so that exposed product does not come in contact with posts, walls, and other fixed parts of the building, or with barrels, boxes, and other containers trafficked through holding and operating areas. Exposed product shall not be placed or stored beneath carcasses in coolers or holding area.

(§ 310.21 continued)

(d) Testing of carcases:

(1) The inspector shall test all carcasses as prescribed in paragraph (c).

(2) Upon initiation of this program at an establishment, the inspector shall begin the testing rate for carcasses from healthy-appearing certified and noncertified calves at Level D as prescribed in paragraph (c)(4). The inspector shall increase the testing rate to the next higher level the following business day when three carcasses in 100 or less consecutively tested show a positive test result for a drug residue. The inspector shall decrease it to the next lower level when no more than two calves show a positive test result for a drug residue in either 500 calves consecutively tested or all calves tested over a 60 working day period.

(3) Test results shall be determined by the veterinary medical officer.

(4) The establishment may designate one or more of its employees to aid the inspector in performing the swab bioassay test under the supervision of the veterinary medical officer who shall interpret the results, maintain animal identification with the test unit, and ensure integrity of the testing program.

(5) all carcasses and parts thereof from calves selected for testing shall be retained until all test results are complete.

(6) The veterinary medical officer shall condemn all carcasses and parts thereof for which there are positive test results and release for human consumption all carcasses and parts thereof for which there are negative test results.

(7) If there is a positive test result, subsequent calves from the producer of the calf shall be tested in accordance with paragraph (e) of this section. These test results will not be included in computations to determine an establishment's compliance record.

(8) The veterinary medical officer may reduce inspection line rates when, in his/her judgment, the prescribed testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for extensive testing.

(e) Calves from producers with a previous residue condemnation. The inspector shall perform a swab bioassay test on all carcasses of all calves in the group. The veterinary medical officer shall determine the test results and shall condemn any carcass and parts thereof for which there is a positive test result and pass for human consumption any such carcass and parts thereof for which there is a negative test result. All subsequent calves from the same producer which has previously sold or delivered to official establishments any carcass that was condemned because of drug residues must be tested according to this paragraph until five consecutive animals test completely free of animal drug residues.

(f) If the owner or operator of an official establishment disagrees with the veterinary medical officer's disposition of carcasses and parts thereof, the owner or operator may appeal as provided in section 306.5 of this chapter.

§ 310.23 Identification of carcasses and parts of swine.

(a) The identification of the carcasses and parts of swine identified in accordance with Part 71 of this title shall be made available to the inspector upon the inspector's request throughout post-mortem inspection.

(b) If the establishment fails to provide required swine identification, the inspector shall order the retention of swine carcasses at the establishment until the completion of tests to confirm that the carcasses are not adulterated.

§ 310.25 Contamination with microorganisms; pathogen reduction performance standards for Salmonella.

(a) Criteria for verifying process control; E. coli testing.

(1) Each official establishment that slaughters cattle and/or swine shall test for Escherichia coli Biotype 1 (E. coli). Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) Sample collection. The establishment shall collect samples from all chilled swine or cattle carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples shall be collected by either sponging or excising tissue from three sites on the selected carcass. On cattle carcasses, establishments shall sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments shall take samples by sponging from inside the flank, inside the brisket, and inside the rump; on swine carcasses, establishments shall sponge or excise tissue from the ham, belly and jowl areas.[1]

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[1]A copy of FSIS's "Guidelines for E. coli Testing for Process Control verification in Cattle and Swine Slaughter Establishments" is available for inspection in the FSIS Docket Room.

* (iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the volume of production at the following rates:
* Cattle: 1 test per 300 carcasses, but at a minimum one sample each week of operation.
* Swine: 1 test per 1,000 carcasses, but at a minimum one sample each week of operation.
* (iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,
* (A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,
* (B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.
* (v) Sampling in very low volume establishments.
* (A) Very low volume establishments annually slaughter no more than 6,000 cattle, 20,000 swine, or a combination of cattle and swine not exceeding 6,000 cattle and 20,000 total of both types. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.
* (B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.
* (3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally

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* [2]A copy of the current edition/revision of the "Official Methods of AOAC International," 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417.

* recognized protocol on collaborative trials and compared against the three tube Most Probable * * Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the * * appropriate MPN index. *

* (4) Recording of test results. The establishment shall maintain accurate records of all * * test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded * * onto a process control chart or table showing at least the most recent 13 test results, by type of * * livestock slaughtered. Records shall be retained at the establishment for a period of 12 months * * and shall be made available to FSIS upon request. *
* (5) Criteria for evaluation of test results. *

* (i) An establishment excising samples from carcasses is operating within the criteria * * when the most recent E. coli test result does not exceed the upper limit (M), and the number of * * samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 * * samples (n) taken, as follows: *

* TABLE 1 - EVALUATION OF E. coli TEST RESULTS *

Type of Livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Cattle	negative [a]	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000 CFU/cm^2	13	3

* [a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least * * 5 cfu/cm^2 carcass surface area. *

* (ii) Establishments sponging carcasses shall evaluate E. coli test results using statistical * * process control techniques. *
* (6) Failure to meet criteria. Test results that do not meet the criteria described in * * paragraph (a)(5) of this section are an indication that the establishment may not be maintaining * * process controls sufficient to prevent fecal contamination. FSIS shall take further action as * * appropriate to ensure that all applicable provisions of the law are being met. *

(§ 310.25 continued)

* (7) Failure to test and record. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

* (b) Pathogen reduction performance standard; Salmonella.

* (1) Raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	N.A.[b]	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

[3] A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(§ 310.25 continued)

* (ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

* (iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

PART 311-DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 311.1 Disposal of diseased or otherwise adulterated carcasses and parts; general.

(a) The carcasses or parts of carcasses of all animals slaughtered at an official establishment and found at the time of slaughter or at any subsequent inspection to be affected with any of the diseases or conditions named in this part shall be disposed of according to the section pertaining to the disease or condition: provided, That no product shall be passed for human food under any such section unless it is found to be otherwise not adulterated. Products passed for cooking or refrigeration under this part must be so handled at the official establishment where they are initially prepared unless they are moved to another official establishment for such handling or in the case of products passed for refrigeration are moved for such refrigeration a freezing facility approved by the Administrator in specific cases: Provided, that when so moved the products are shipped in containers sealed in accordance with §318.10© of this subchapter or in a sealed means of conveyance as provided in § 325.7 of this subchapter. Owing to the fact that it is impracticable to formulate rules covering every case and to designate at just what stage a disease process or a condition results in adulteration of a product, the decision as to the disposal of all carcasses, organs, or other parts not specifically covered in this part shall be left to the veterinary medical officer. The veterinary medical officer shall exercise his judgement regarding the disposition of all carcasses or parts of carcasses under this part in a manner which will insure that only wholesome, unadulterated product is passed for human food.

(b) In cases of doubt as to a disease, or the cause of a condition, or to confirm a diagnosis, representative specimens of the affected tissues, properly prepared and packaged, shall be sent for examination to one of the laboratories of the Biological Control Section of the Program.

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§320.4 Access to and inspection of records, facilities, and inventory; copying and sampling.

Every person (including every firm or corporation) within any of the classes specified in § 320.1 shall upon the presentation of official credentials by any duly authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by § 320.1 and the facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records and to take reasonable samples of the inventory upon payment of the fair market value therefor. Any necessary facilities (other than reproduction equipment) for such examination and copying of records and for such examination and sampling of inventory shall be afforded to such authorized representative of the Secretary.

§ 320.5 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business in or for commerce, as a meat broker, renderer, or animal food manufacturer, or engages in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, or any livestock, whether intended for human food or other purposes, or engages in business as a public warehouseman storing any such articles in or for commerce, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any such livestock that died otherwise than by slaughter, shall register with the Administrator, giving such informaiton as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business, by filing with Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, a form containing such information within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from the Compliance Program, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

§ 320. 6 Information and reports required from official establishment operators.

* (a) The operator of each official establishment shall furnish to Program employees *
* accurate information as to all matters needed by them for making their daily reports of the *
* amount of products prepared or handled in the departments of the establishment to which they *
* are assigned and such reports concerning sanitation, mandatory microbiological testing, and *
* other aspects of the operations of the establishment and the conduct of inspection, as may be *
* required by the Administrator in special cases. *

(b) The operator of each official establishment shall report quarterly the number of pounds of meat and meat food product produced at that establishment. The report shall be made on a form furnished by the Administrator and shall be submitted to an inspector at the establishment. Each report shall cover a calendar quarter and shall be filed within 15 days after the end of each quarter.

(c) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

§ 320.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the Inspector in Charge, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity, source, and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for sale or transportation, or receive for transportation, in commerce, any such product which is capable of use as human food and is adulterated or misbranded at the time of such sale, transportation, offer, or receipt: Provided, however, That any such allegedly adulterated or misbranded product may be transported to the official establishment from which it had been transported, in accordance with § 325.10 of this subchapter.

Part 321-COOPERATION WITH STATES AND TERRITORIES

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 321.1 Assistance to State and Territorial programs.

(a) The Administrator is authorized under paragraph (a) of section 301 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any state (including Puerto Rico) or any organized Territory in developing and administering the meat inspection program of such jurisdiction with a view to assuring that it imposes and enforces requirements at least equal to those under Titles I and IV of the Act, with respect to establishments at which products are prepared for use as human food solely for distribution within such jurisdiction, and with respect to the products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a law imposing mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements at least equal to the Federal requirements with respect to all or certain classes of persons engaged in slaughtering livestock or otherwise preparing products solely for distribution within such jurisdiction.

(§ 327.1 continued)

(b) The provisions of this part shall apply to products derived from cattle, sheep, swine, goats, horses, mules, and other equines, if capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in Parts 94, 95, and 96 of Chapter I of this Title.

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

(a)(1) When it shall be determined by the Administrator that the system of meat inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their products with requirements equivalent to all the inspection, building construction standards, and all other provisions of the Act and the regulations in this subchapter which are applied to official establishments in the United States, and their products, and that reliance can be placed upon certificates required under this part from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, products prepared in such establishments which are certified and approved in accordance with paragraph (a)(3) of this section, shall be eligible so far as this subchapter is concerned for importation into the United States from such foreign country after applicable requirements of this subchapter have been met.

(2) The determination of acceptability of a foreign meat inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foregin country. The system as implemented must provide standards equivalent to those of the Federal system of meat inspection in the United States with respect to:

* (A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which products prepared for export to the United States; *

* (B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system; *

* (C) The assignment of competent, qualified inspectors; *

* (D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing meat inspection and to certify or refuse to cerify products intended for export; *

* (E) Adequate administrative and technical support; *

* (F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States; *

* (G) Other requirements of adequate inspection service as required by the regulations in this subchapter. *

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of meat inspection organized and maintained in the United States with respect to:

* (A) Ante-mortem inspection of animals for slaughter, and inspection of methods of slaughtering and handling in connection with slaughtering which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of veterinarians; *

* (B) Post-mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians; *

* (C) Official controls by the national government over establishment construction, facilities, and equipment; *

* (D) Direct and continuous official supervision of slaughtering and preparation of product, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section, to assure that adulterated or misbranded product is not prepared for export to the United States; *

* (E) Complete separation of establishments certified under paragraph (a)(3) of this section from establishments not certified and the maintenance of a single standard of inspection and sanitation throughout all certified establishments; *

* (F) Requirements for sanitation at certified establishments and for sanitary handling of product; *

* (G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment; *

* (H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter. *

* (I) Other matters for which requirements are contained in the Act or regulations in this subchapter. *

(iii) Countries desiring to establish eligibility for importation of product into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign meat inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2)(i) and (ii) of this section. Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a)(2)(i) and (ii) of this section. Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system, including information required by paragraph (e) of section 20 of the Act, as the Administrator may find pertinent to and necessary for the determinations required by this section of the regulations.

(iv) The foregin inspection system must maintain a program to assure that the requirements referred to in this section, "equivalent to" those of the Federal system of meat inspection in the United States, are being met. The program as implemented must provide for the following:

TITLE 9 - ANIMALS AND ANIMAL PRODUCTS

CHAPTER III - ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(MEAT AND POULTRY INSPECTION)

DEPARTMENT OF AGRICULTURE

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(2) However, certification under subsection 21(b) of the Federal Water Pollution Control Act is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification or to meet the other requirements of subsection 21(b) prior to April 1, 1973, will result in the termination of inspection at such facilities on that date.

(3) Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

* § 381.22 Conditions for receiving inspection. *

* (a) Before being granted Federal inspection, an establishment shall have developed *
* written sanitation Standard Operating Procedures, in accordance with Part 416 of this chapter. *
* (b) Before being granted Federal inspection, an establishment shall have conducted a *
* hazard analysis and developed and validated a HACCP plan, in accordance with *
* §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period *
* not to exceed 90 days, during which period the establishment must validate its HACCP plan. *
* (c) Before producing new product for distribution in commerce, an establishment shall *
* have conducted a hazard analysis and developed a HACCP plan applicable to that product in *
* accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the *
* new product is produced for distribution in commerce, the establishment shall validate its *
* HACCP plan, in accordance with § 417.4 of this chapter. *

Subpart E-Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

§ 381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

§ 381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

§ 381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under Subpart C and comply with all requirements of said subpart.

§ 381.28 Report of violations.

Each inspector, agent, representative, or employee of the Inspection Service shall report, in the manner prescribed by the Administrator, all violations of the Act and noncompliance with the regulations of which he has knowledge.

§ 381.29 Suspension or other withdrawal of inspection service.

(a) Inspection service may be withdrawn in accordance with section 18 of the Act and the applicable rules of practice.

(b) During a period of withdrawal, no processing of poultry or poultry products subject to the inspection requirements of the Act shall be carried on in the official establishment. However, any product which was inspected and passed prior to the withdrawal may be shipped from the official establishment, provided its identity was maintained, and it has not become adulterated or misbranded.

(c) Inspection may be suspended, revoked, or terminated as provided in subsection 21(b) of the Federal Water Pollution Control Act, as amended.

(d) The assignment of inspectors may be temporarily suspended, in whole or in part, by the Administrator, to the extent he determines necessary to avoid impairment of the effective conduct of the inspection service when the operator of any official establishment or any subsidiary therein, or any officer, employee, or agent of any such operator or any subsidiary therein, acting within the scope of his office, employment, or agency , threatens to forcibly assault or forcibly assaults, intimidates, or interferes with any inspection service

(§ 381.29(d) continued)

employee in or on account of the performance of his official duties under the Act, unless promptly upon the incident being brought by an authorized supervisor of the Inspection Service employee to the attention of the operator of the establishment the operator (1) satisfactorily justifies the incident, (2) takes effective steps to prevent a recurrence, or (3) provides acceptable assurance that there will not be any recurrences. The suspension shall remain in effect until one of such actions is taken by the operator: Provided, that upon request of the operator he shall be afforded an opportunity for an expedited hearing to show cause why the suspension should be terminated.

Subpart F-Assignment and Authorities of Program Employees

§ 381.30 - 381.31 (RESERVED)

§ 381.32 Access to establishments.

Any duly authorized representative of the Secretary shall have access at all reasonable times, by day or night, whether the establishment is in operation or not, to the premises or any part thereof of an establishment engaged in processing poultry or poultry products for commerce, upon presentation of appropriate credentials.

§ 381.33 Identification.

Each inspector will be furnished with a numbered official inspection badge, which shall remain in his or her possession at all times, and which shall be worn in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle the inspector to admittance at all regular entrances and to all parts of the establishment and premises to which the inspector is assigned.

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§ 381.45 Minimum standards for sanitation, facilities and operating procedures in official establishments.

* The provisions of §§ 381.46 to 381.61, inclusive, and part 416 of this chapter shall apply with respect to all official establishments. *

§ 381.46 Buildings.

(a) General. The buildings shall be of sound construction and kept in good repair.

(b) Outside openings. (1) The doors, windows, skylights, and other outside openings of the plant, except in receiving rooms and feeding rooms, shall be protected by properly fitted screens or other suitable devices against the entrance of flies and other insects.

(2) Outside doors, except in receiving rooms and feeding rooms, shall be so hung as to be close fitting when closed. Doors shall be provided with self-closing devices where necessary to prevent the entry of vermin into processing and storage rooms.

§ 381.47 Rooms and compartments.

(a) General. Rooms or compartments used for edible poultry products shall be separate and distinct from inedible products departments and from rooms where live poultry is held or slaughtered. Separate rooms shall be provided when required for conducting processing operations in a sanitary manner; and all rooms shall be of sufficient size to permit the installation of the necessary equipment for processing operations and the conduct of such operations in a sanitary manner.

(b) Refuse rooms. A Separate refuse room, or other equally adequate facilities, shall be provided in official establishments where accumulations of refuse occur. Refuse rooms shall be entirely separate from other rooms in the establishment, have tight-fitting doors, be properly ventilated, and have adequate drainage and cleanup facilities, and the floors and walls to a height of 6 feet above the floor shall be impervious to moisture, and walls above that height, and ceilings shall be moisture resistant.

(c) Rooms for holding carcasses for further inspection. Rooms or other acceptable facilities in which carcasses or parts thereof are held for further inspection shall be in such numbers and such locations as the needs of the inspection in the establishment may require. These rooms or facilities shall be equipped with hasps for locking.

(d) Coolers and freezers. Coolers and freezers shall be of such size and capacity as are required for compliance with the provisions set forth in § 381.66. Freezing rooms, other than those for plate freezers or liquid freezing, shall have forced air circulation, and freezers and coolers shall be equipped with floor racks, pallets or other means which will assure that the poultry products will not be adulterated.

(e) Room for mechanical deboning of raw poultry. Rooms or compartments where mechanical equipment for deboning of raw poultry is operated shall be maintained at 50°F. Or less.

(§ 381.47 continued)

(f) Storage and supply rooms. The storage and supply rooms shall be kept in good repair, dry, orderly, and sanitary.

(g) Boiler room. The boiler room shall be a separate room where necessary to prevent dirt and objectionable odors entering from it into any room where dressed poultry or other poltry products are processed, otherwise handled, or stored.

(h) Toilet rooms. Toilet rooms, opening directly into rooms where poultry products are exposed shall have self-closing doors and shall be ventilated to the outside of the building.

(i) Lunch rooms. Lunches and snacks shall not be eaten in processing, packing, or supply rooms. If needed, separate rooms or areas shall be provided in establishment where employees eat their lunches.

§ 381.48 Floors, walls, ceilings, etc.

(a) Floors. All floors in rooms where exposed poultry products are processed or handled shall be constructed of, or finished with, materials impervious to moisture, so they can be readily and thoroughly cleaned. The floors in killings, ice cooling, ice packing, eviscerating, cooking, boning, and cannery rooms shall be graded for complete runoff with no standing water.

(b) Walls, posts, partitions, doors. All walls, posts, partitions, and doors in rooms where exposed poultry products are processed or otherwise handled shall be smooth and constructed or materials impervious to moisture to a height of 6 feet above the floor to enable thorough cleaning. All surfaces above this height must be smooth and finished with moisture-resistant material.

(c) Ceilings. Ceilings must be moisture resistant in rooms where exposed poultry products are processed or otherwise handled, and finished and sealed to prevent collection of dirt or dust that might sift through from the floor above or fall from collecting surfaces on equipment or exposed poultry product.

§ 381.49 Drainage and plumbing.

(a) General. There shall be an efficient draining and plumbing system for the plant and premises.

§ 381.92 Overscald.

Carcasses of poultry which have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned.

§ 381.93 Decomposition.

Carcasses of poultry deleteriously affected by post-mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) Any part of a carcass which is green struck shall be condemned and, if the carcass is so extensively affected that removal of affected parts is impracticable, the whole carcass shall be condemned.

(c) Carcasses affected by types of post-mortem change which are superficial in nature may be passed for human food after removal and condemnation of the affected parts.

* § 381.94 Contamination with Microorganisms; process control verification criteria and testing; *
* pathogen reduction standards. *

* (a) Criteria for verifying process control; E. coli testing. *
* (1) Each official establishment that slaughters poultry shall test for Escherichia coli *
* Biotype I (E. coli). Establishments that slaughter more than one type of poultry and/or poultry *
* and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The *
* establishment shall: *
* (i) Collect samples in accordance with the sampling techniques, methodology, and *
* frequency requirements in paragraph (a)(2) of this section; *
* (ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and *
* (iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this *
* section. *
* (2) Sampling requirements. *
* (i) Written procedures. Each establishment shall prepare written specimen collection *
* procedures which shall identify employees designated to collect samples, and shall address *
* location(s) of sampling, how sampling randomness is achieved, and handling of the sample to *
* ensure sample integrity. The written procedure shall be made available to FSIS upon request. *
* (ii) Sample collection. Samples shall be collected by taking a whole bird from the end of *
* the chilling process, after the drip line, and rinsing it in an amount of buffer appropriate to the *
* type of bird being tested. If the bird is boned before chilling (hot boned poultry), the sample shall *
* be taken from the end of the slaughter line instead of the end of the drip line.[4] *

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* [1]A copy of FSIS's "Sampling Technique for E. coli in Raw Meat and Poultry for *
* Process Control Verification" is available for inspection in the FSIS Docket Room. *

* (iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, shall take samples at a frequency proportional to the establishment's volume of production at the following rates:
* Chickens: 1 sample per 22,000 carcasses, but at a minimum one sample per each week of operation.
* Turkeys: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation
* (iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,
* (A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,
* (B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.
* (v) Sampling in very low volume establishments.
* (A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments slaughtering turkeys in the largest number shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(I) of this section.
* (B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

* (3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the

(§ 381.94 continued)

* Association of Official Analytical Chemists)[5] or approved and published by a scientific body and *
* based on the results of a collaborative trial conducted in accordance with an internationally *
* recognized protocol on collaborative trials and compared against the three tube Most Probable *
* Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the *
* appropriate MPN index. *
* (4) Recording of test results. The establishment shall maintain accurate records of all *
* test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control *
* chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. *
* Records shall be retained at the establishment for a period of 12 months and shall be made *
* available to FSIS upon request. *
* (5) Criteria for Evaluation of test results. *
* (i) An establishment is operating within the criteria when the most recent E. coli test *
* result does not exceed the upper limit (M), and the number of samples, if any, testing positive at *
* levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows: *

TABLE 1 - EVALUATION OF E. coli TEST RESULTS

Types of Poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Chickens	100 CFU/ml	1,000 CFU/ml	13	3
Turkeys	N.A.[a]	N.A.	N.A.	N.A.

* [a] Not available; values for turkeys will be added upon completion of data collection program for *
* turkeys. *

* (ii) For types of poultry appearing in paragraph (a)(5)(i) Table 1 of this section that do not *
* have m/M criteria, establishments shall evaluate E. coli test results using statistical process *
* control techniques. *
* (6) Failure to meet criteria. Test results that do not meet the criteria described in *
* paragraph (a)(5) of this section are an indication that the establishment may not be maintaining *
* process controls sufficient to prevent fecal contamination. FSIS shall take further action as *
* appropriate to ensure that all applicable provisions of the law are being met. *

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* [2]A copy of the current edition/revision of the "Official Methods of AOAC International," *
* 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and *
* may be purchased from the Association of Official Analytical Chemists International, Inc., 481 *
* North Frederick Ave., Suite 500, Gaithersburg, MD 20877-2417. *

(7) Failure to test and record. Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a)(1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; Salmonella.

(1) Raw poultry product performance standards for Salmonella.

(i) An establishment's raw poultry products, when sampled and tested by FSIS for Salmonella as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2 - SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers	20.0% [b]	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	N.A.[b]	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; baseline targets for turkeys will be added upon completion of the data collection programs for that product.

(2) Enforcement. FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of Salmonella in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[6]

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[3]A copy of FSIS's "Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Raw Meat and Poultry Products" is available for inspection in the FSIS Docket Room.

(§ 381.94 continued)

* (3) Noncompliance and establishment response. When FSIS determines that an *
* establishment has not met the performance standard: *
* (i) The establishment shall take immediate action to meet the standard. *
* (ii) If the establishment fails to meet the standard on the next series of compliance tests *
* for that product, the establishment shall reassess its HACCP plan for that product. *
* (iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this *
* section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests *
* for that product, constitutes failure to maintain sanitary conditions and failure to maintain an *
* adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will *
* cause FSIS to suspend inspection services. Such suspension will remain in effect until the *
* establishment submits to the FSIS Administrator or his/her designee satisfactory written *
* assurances detailing the action taken to correct the HACCP system and, as appropriate, other *
* measures taken by the establishment to reduce the prevalence of pathogens. *

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wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes, or engages in the business as a public warehouseman storing any such articles in or for commerce, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, shall register with the Administrator, giving such information as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business. Such persons shall register under this section by filing with the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, a form containing such information within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from the Compliance Program, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

§ 381.180 Information and reports required from official establishment operators.

* (a) The operator of each official establishment shall furnish to Program employees *
* accurate information as to all matters needed by them for making their daily reports of the *
* amount of products prepared or handled in the departments of the establishment to which they *
* are assigned and such reports concerning sanitation, mandatory microbiological testing, and *
* other aspects of the operations of the establishment and the conduct of inspection thereat, as may *
* be required by the Administrator in special cases. *

(b) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

§ 381.181 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any poultry product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the appropriate program supervisor, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity, source and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for

sale or transportation or receive for transportation, in commerce, any such product which is capable of use as human food and is in fact adulterated or misbranded at the time of such sale, transportation, offer, or receipt: Provided, That any such allegedly adulterated or misbranded product may be transported to any official establishment for reinspection.

§ 381.182 Reports of inspection work.

Reports of the inspection work carried on within official establishments shall be forwarded to the Administrator by the inspector in charge in such a manner as may be specified by the Administrator.

Subpart R-Cooperation With States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program

§ 381.185 Assistance to State and Territorial programs.

(a) The Administrator is authorized, under paragraph (a) of section 5 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering the poultry product inspection program of such jurisdiction, with a view to assuring that it imposes and enforces requirements at least equal to those under sections 2 through 4, 6 through 10, and 12 through 22 of the Act, with respect to establishments at which poultry are slaughtered or poultry products are processed for use as human food, solely for distribution within such jurisdiction, and with respect to the poultry products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a mandatory law imposing ante-mortem and post-mortem inspection, reinspection, and sanitation requirements (at least equal to those under the Federal Act), with respect to all or certain classes of persons engaged in slaughtering poultry or otherwise processing poultry products for use as human food solely for distribution within such jurisdiction.

(b) The Administrator is also authorized under paragraph (a) of section 5 of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering programs under the laws of such jurisdiction containing authorities at least equal to those provided in section 11 of the Act (relating to records; registration of specified classes of operators; dead, dying, disabled, or diseased poultry; and products not intended for human food) when he determines that such cooperation would effectuate the purposes of the Act.

(c) Such cooperation may include advisory assistance, technical and laboratory assistance and training, and financial aid. The Federal contribution to any State (or territory) for any year shall not exceed 50 percent of the estimated total cost of the cooperative State (or territorial) program. A cooperative program under this section is called a State-Federal program.

(§ 381.195(a) continued)

(1) Import (Imported). To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) For product from eligible countries other than Canada:

(i) Offer(ed) for entry. The point at which the importer presents the imported product to the Program for reinspection.

(ii) Entry (entered). The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with §327.26 of this part.

(3) For product from Canada:

(i) Offer(ed) for entry from establishments participating in the "streamlined" inspection procedures. The point at which an official of the Canadian inspection system contacts the Import Field Office for an inspection assignment.

(ii) Offer(ed) for entry from nonparticipating establishments. The point at which the importer presents the imported product to the Program for reinspection.

(iii) Entry (entered) for product not subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and upon the filing of Customs Form 7533 at the port of entry or at the nearest customshouse in accordance with 19 CFR Part 123.

(iv) Entry (entered) for product subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and the foreign inspection certificate accompanying the product is stamped as "Inspected and Passed" by the import inspector.

(b) No slaughtered poultry, or parts or products thereof, shall be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and they also comply with the regulations prescribed in this subpart to assure that they comply with the stardards provided for in the Act: Provided, That the provisions of this subpart apply to such articles only if they are capable of use as human food.

(c) Except as provided in § 381.207, slaughtered poultry and other poultry products may be imported only if they were processed solely in countries listed in § 381.196(b). Slaughtered poultry may be imported only if it qualifies as ready-to-cook poultry.

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a) (1) Whenever it shall be determined by the Administrator that the system of poultry inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their poultry products, with requirements equivalent to all the provisions of the Act and the regulations in this part which are applied to official establishments in the United States, and their

poultry products, and that reliance can be placed upon certificates required under this subpart from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, poultry products processed in such establishments which are certified and approved in accordance with paragraph (a)(3) of this section shall be eligible, so far as the regulations in this part are concerned, for importation into the United States from such foreign country after applicable requirements of this part have been met.

(2) The determination of acceptability of a foreign poultry inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of poultry inspection in the United States with respect to:

* (A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which poultry products are processed for export to the United States; *

* (B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system; *

* (C) The assignment of competent, qualified inspectors; *

* (D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing poultry inspection and to certify or refuse to certify poultry products intended for export; *

* (E) Adequate administrative and technical support; *

* (F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States; *

* (G) Other requirements of adequate inspection service as required by the regulations. *

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of poultry inspection organized and maintained in the United States with respect to:

* (A) Ante-mortem inspection of poultry for slaughter, which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of veterinarians; *

* (B) Post-mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licenses of the system under the direct supervision of veterinarians; *

* (C) Official controls by the national government over establishment construction, facilities, and equipment; *

* (D) Direct and continuous official supervision of slaughtering of poultry and processing of poultry products, by the assignment of inspectors to establishments certified under *

paragraph (a)(3) of this section to assure that adulterated or misbranded poultry products are not processed for export to the United States Government;

* (E) Complete separation of establishments certified under paragraph (a) (3) of this section from establishments not certified, and the maintenance of a single standard of inspection and sanitation throughout all certified establishments; *

* (F) Requirements for sanitation at certified establishments and for sanitary handling of poultry products; *

* (G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment; *

* (H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter. *

* (I) Other matters for which requirements are contained in the Act or the regulations in this part. *

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TITLE 9 - ANIMALS AND ANIMAL PRODUCTS

CHAPTER III - FOOD SAFETY AND INSPECTION SERVICE
(MEAT AND POULTRY INSPECTION)

DEPARTMENT OF AGRICULTURE

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SUBCHAPTER E -- REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

Authority: 21 U.S.C. 451-470, 601-695; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53.

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initiatlly implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

* Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

* § 416.15 Corrective Actions.

* (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).
(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

* § 416.16 Recordkeeping requirements.

* (a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.
(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.
(c) Records required by this part shall be maintained for at least 6 months and made accesable available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

* § 416.17 Agency verification.

* FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

* (a) Reviewing the Sanitation SOP's;
(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(§ 416.17 continued)

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417--Hazard Analysis and Critical Control Point (HACCP) Systems

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

* (3) Food safety hazards might be expected to arise from the following: *
* (i) Natural toxins; *
* (ii) Microbiological contamination; *
* (iii) Chemical contamination; *
* (iv) Pesticides; *
* (v) Drug residues; *
* (vi) Zoonotic diseases; *
* (vii) Decomposition; *
* (viii) Parasites; *
* (ix) Unapproved use of direct or indirect food or color additives; and *
* (x) Physical hazards. *
* (b) The HACCP plan. (1) Every establishment shall develop and implement a written *
* HACCP plan covering each product produced by that establishment whenever a hazard analysis *
* reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard *
* analysis conducted in accordance with paragraph (a) of this section, including products in the *
* following processing categories: *
* (i) Slaughter--all species *
* (ii) Raw product--ground *
* (iii) Raw product--not ground *
* (iv) Thermally processed--commercially sterile *
* (v) Not heat treated--shelf stable *
* (vi) Heat treated--shelf stable *
* (vii) Fully cooked--not shelf stable *
* (viii) Heat treated but not fully cooked--not shelf stable *
* (ix) Product with secondary inhibitors--not shelf stable *
* (2) A single HACCP plan may encompass multiple products within a single processing *
* category identified in this paragraph, if the food safety hazards, critical control points, critical *
* limits, and procedures required to be identified and performed in paragraph (c) of this section are *
* essentially the same, provided that any required features of the plan that are unique to a specific *
* product are clearly delineated in the plan and are observed in practice. *
* (3) HACCP plans for thermally processed/commercially sterile products do not have to *
* address the food safety hazards associated with microbiological contamination if the product is *
* produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of *
* this chapter. *
* (c) The contents of the HACCP plan. The HACCP plan shall, at a minimum: *
* (1) List the food safety hazards identified in accordance with paragraph (a) of this *
* section, which must be controlled for each process. *
* (2) List the critical control points for each of the identified food safety hazards, *
* including, as appropriate: *
* (i) Critical control points designed to control food safety hazards that could be *
* introduced in the establishment: and, *

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point.

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 608 and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(§ 417.3(b) continued)

* (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
* (2) Perform a review to determine the acceptability of the affected product for distribution;
* (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
* (4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
* (c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

* § 417.4 Validation, Verification, Reassessment.

* (a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.
* (1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
* (2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:
* (i) The calibration of process-monitoring instruments;
* (ii) Direct observations of monitoring activities and corrective actions; and
* (iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.
* (3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(§ 417.4 continued)

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(§417.5 continued)

* (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.
* (f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

* § 417.6 Inadequate HACCP Systems. A HACCP system may be found to be inadequate if:

* (a) The HACCP plan in operation does not meet the requirements set forth in this part;
* (b) Establishment personnel are not performing tasks specified in the HACCP plan;
* (c) The establishment fails to take corrective actions, as required by § 417.3 of this part;
* (d) HACCP records are not being maintained as required in § 417.5 of this part; or
* (e) Adulterated product is produced or shipped.

* § 417.7 Training.

* (a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:
* (1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and
* (2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.
* (b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

* § 417.8 Agency Verification.

* FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:
* (a) Reviewing the HACCP plan;
* (b) Reviewing the CCP records;
* (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
* (d) Reviewing the critical limits;
* (e) Reviewing other records pertaining to the HACCP plan or system;

(§ 417.8 continued)

* (f) Direct observation or measurement at a CCP; *
* (g) Sample collection and analysis to determine the product meets all safety standards; *
* and *
* (h) On-site observations and record review. *

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